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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,475	07/27/2001	Brian D. Andresen	IL-10380	1094

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EXAMINER
ROGERS, DAVID A

ART UNIT	PAPER NUMBER
2856	

DATE MAILED: 03/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/917,475	ANDRESEN ET AL.	
	Examiner	Art Unit	
	David A. Rogers	2856	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) __ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Objections

1. Claim 17 is objected to because of the following informality. Line 2 of claim 17 states "piercing operation with damage to said tube". It has been assumed that the applicant's intent was to claim piercing without damaging the tube, and the application has been examined in this manner. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by "Direct Solid Phase Microextraction of Complex Aqueous Samples With Hollow Fiber Membrane Protection" to Zhang *et al.* Zhang discloses that it is highly desirable to protect a fiber of a solid phase microextraction (SPME) device. Zhang further discloses that, in order to protect the fiber, a porous membrane is placed around the fiber such that it forms a concentric, protective sheath about the fiber. The sheath allows specific analytes to reach the fiber, but excludes other materials. The fiber is the active extraction media as is well known to one of ordinary skill in the art of SPME.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,693,228 to Koehler *et al.* in view of U.S. Patent 6,042,787 to Pawliszyn. Koehler teaches a syringe (reference item 42) for performing SPME comprising a needle (reference item 44) with a pointed tip (reference item 58), a metal tubular casing (reference item 57) with an open, flat end, and a fiber (reference item 46) inside the casing that passes through the open end, as best seen in Figure 2A. The purpose of the casing is to protect the fiber from damage and ensure a good seal (column 4, lines 29-31). Furthermore, though not expressly disclosed, the metal casing would have strength sufficient to pierce a septum. Koehler's SPME syringe is a standard device as is well known in the art. In using the syringe of Koehler, the needle is inserted through a septum (reference item 32) and the syringe is mounted to a movable frame. The syringe, after being mounted to a frame and having the fiber extracted from within the needle and casing, is subjected to oscillatory movements by a vibrator (reference item 10) in order to increase the adsorption rate. Koehler recognizes, in prior art syringes, that the stirring or rotating motion of the vial containing the analyte may be of sufficient force to break the vial (column 2, lines 36-46 and 51-61). One of ordinary skill in the art would clearly recognize that, if the stirring or rotating is of sufficient magnitude to break the vial, then there might well be sufficient force to cause damage to the thin, delicate fiber. Koehler, however, does not teach a porous tube that is porous and still contains and protects the active extraction fiber. Pawliszyn teaches a syringe (reference item 4) for SPME that is similar in design to that of Koehler and comprises a needle (reference item 18) with a tip (reference item 28), a protective metal sheath (reference item 24)

with an open, flat end, and a fiber (reference item 6) that passes though the open, flat end, as best seen in Figure 2. The purpose of the metal sheath is to protect the fiber from damage and ensure a good seal (column 3, lines 14-16). Furthermore, though not expressly disclosed, the metal sheath would have strength sufficient to pierce a septum. In another embodiment, Pawliszyn teaches that it is desired to further protect a fiber (reference item 62) using a tubular shield (reference item 108) with perforations (reference item 110) that extends beyond the end of the fiber, as best seen in Figure 14. The perforations, either being circular or non-circular, extend along the tube's full length thus allowing the full range of the sampling zone (reference item 80) of the fiber to be exposed and protected. Pawliszyn, however, does not teach the use of the porous tube on a syringe. Clearly, both Koehler and Pawliszyn recognize the need to fully protect the fiber using a metal casing, and yet still ensure that sufficient analyte is directed to the fiber. Since, in the SPME device of Figure 2 of Pawliszyn, it is desired to protect the fiber using a tubular casing and still allow the analyte to reach the fiber, it would have been obvious to replace the solid tubular casing of either Pawliszyn or Koehler with the perforated casing in order to fully protect the fiber and yet still allow sufficient analyte to reach the fiber. This is especially true in view of the teachings of Koehler where the delicate fiber is subjected to oscillatory movements in order to decrease the adsorption time, and where these oscillatory movements are known to cause damage. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Koehler with the teachings of Pawliszyn to obtain a device for use in SPME comprising a needle, a fiber with active extraction media, and a porous, tubular casing that generally surrounds the fiber thus allowing the analyte to reach the fiber yet also allowing the fiber to be protected from the surrounding environment.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a. U.S. Patent 5,432,098 to Wilks discloses a needle (reference item 212_1) comprising a closed, sharp point (reference item 212_{1D}) and a plurality of holes (reference item 212_{1E}) for sampling; and

b. U.S. Patent 5,938,939 to Vial *et al.* discloses a needle (reference item 12), comprising a plurality of circular (reference item 9) or non-circular holes (reference item 10), that pierces a septum (reference item 3). The holes allow larger particles to be filtered out while liquid and smaller particles pass through.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Rogers whose telephone number is (703) 305-4451. The examiner can normally be reached on Monday - Friday (0730 - 1600).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron E. Williams can be reached on (703) 305-4705. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7722 for regular communications and (703) 872-9319 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 306-3431.

dar
February 25, 2003

HELEN KWOK
PRIMARY EXAMINER